IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9147

Bartle, J. September 23, 2013

Robert Chapman ("Mr. Chapman"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] and Mr. Chapman's Estate ("Estate"), a representative class member under the Settlement Agreement, seek benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether Mr. Chapman or his Estate has demonstrated a reasonable medical basis to support their

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Jamie G. Chapman ("Ms. Chapman"), Mr. Chapman's spouse, also has submitted a derivative claim for benefits.

respective claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

To seek Matrix Benefits, a claimant or a representative claimant[4] must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if claimant or the representative claimant is represented by an attorney, the attorney must complete Part III.

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to claimants or representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to claimants or representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators, or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

In May, 2003, Mr. Chapman submitted a completed Green Form to the Trust signed by his attesting physician, Stephen Raskin, M.D., F.A.C.C. Based on an echocardiogram dated December 31, 2002,[5] Dr. Raskin attested in Part II of this Green Form that Mr. Chapman suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[6] Based on such findings, Mr. Chapman would be entitled to Matrix A-1, Level III benefits.[7]

Dr. Raskin declined to answer in this Green Form whether Mr. Chapman suffered from chordae tendineae rupture or papillary muscle rupture or acute myocardial infarction associated with acute mitral regurgitation. Instead, Dr. Raskin referred to a letter he attached to the Green Form. In this letter, Dr. Raskin explained, in pertinent part, that:

> The transesophageal echocardiogram dated 11/7/02 demonstrates a thin, oscillating mass adherent to the mural mitral leaflet. In the context of infective endocarditis and

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5. Although Dr. Raskin noted in claimant's Green Form that he based his responses on an echocardiogram dated December 30, 2002, he subsequently clarified that the echocardiogram actually was performed on December 31, 2002.

6. Dr. Raskin also attested that Mr. Chapman suffered from bacterial endocarditis, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

7. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

> associated coronary embolism (a probable embolic complication of Mr. Chapman's infective endocarditis) the most probable diagnosis of the oscillating mass includes: vegetation, or ruptured chordae tendinae (secondary to infective endocarditis). The subsequent gross anatomical appearance of the mitral valve as described in the 1/7/03 operative note excludes the likelihood of chordal rupture secondary to primary and preexisting mitral valve prolapse. The gross anatomical findings of chordae elongation, interchordal hooding and annular dilation would be expected with chordae rupture secondary to this condition. More likely than not, the present [sic] of mitral valve prolapse and chordae rupture with mild flail of the P2 mural segment would have allowed for simple valvular repair and not valve replacement.

Under the Settlement Agreement, the presence of chordae tendineae rupture requires the payment of reduced Matrix Benefits for a claim for damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c). As the Trust does not contest Mr. Chapman's entitlement to Level III benefits, the only issue before us with respect to this Green Form is whether Mr. Chapman is entitled to payment on Matrix A-1 or the reduced Matrix B-1.

In February, 2004, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for finding that Mr. Chapman did not

suffer from chordae tendineae rupture.[8] In support of her conclusion, Dr. Penkala explained that:

> Even despite the limitations of this study there appears to be a ruptured chord to the posterior [mitral valve] leaflet with a region of prolapse/partial flail. This was subsequently seen much more clearly on the [transesophageal echocardiogram] dated 1/7/03.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that Mr. Chapman was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Chapman contested this adverse determination.[9] In contest, Mr. Chapman argued that there was a reasonable medical basis for Dr. Raskin's findings. In support, Mr. Chapman submitted a sworn statement of Dr. Raskin, wherein he stated, in pertinent part, that:

> A *ruptured chordae tendineae* (most likely as a result of infective endocarditis) is a

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8. Dr. Penkala also concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Chapman did not have mitral valve prolapse. The presence of mitral valve prolapse also requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b). Given our resolution with regard to chordae tendineae rupture, we need not address the issue of mitral valve prolapse.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Chapman's claim.

> possible secondary diagnosis raised by the echocardiographic evaluations. However, a ruptured chordae was not found at the time of direct evaluation of the mitral valve by the surgeon. Furthermore, while the anatomical diagnosis *excluded a ruptured chordae* it raised the issue *of diet drug valvulopathy* and revealed gross anatomical findings consistent with *endocarditis*.
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> ....
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> In summary, the gross anatomical appearance of the mitral valve as described in the 1/7/03 operative report by Dr. E.T. Robbins *excluded chordae rupture secondary to primary and preexisting mitral valve prolapse*. Additionally, the findings of primary mitral prolapse such as: chordae elongation, interchordal hooding and annular dilatation were notably absent in this case. The 1/7/03 operative report did, however, note *valve thickening with color changes similar to published reports of diet drug valvulopathy cases*. Moreover, the valve changes are further described as having "*extensive endocarditic changes on the thickened and discolored valve*." It is reasonable to conclude that if mitral valve prolapse with chordae rupture and mild flail of the mural segment were present, then simple valve repair and not valve replacement would have taken place. Valve replacement was undoubtedly necessary due to "*endocarditic changes over both leaflets*" and the extensive pathology of the mural as well as the anterior mitral leaflet described by Dr. E.T. Robbins as a "*tremendous amount of change in both leaflets secondary to Fen Phen [use]*."
>
> It is my opinion that Mr. Chapman's nearly 3-month exposure to diet drugs caused pathological changes to his mitral valve and secondary mitral regurgitation.

(Emphasis in original.) Finally, Mr. Chapman argued that the auditing cardiologist did not provide a sufficient basis on which the Trust could deny his claim because Dr. Penkala did not

definitively state that Mr. Chapman had chordae tendineae rupture.

The Trust then issued a final post-audit determination, again determining that Mr. Chapman was entitled only to Matrix B-1, Level III benefits. Mr. Chapman disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Chapman's claim should be paid. On August 26, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3879 (Aug. 26, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Mr. Chapman then served a response upon the Special Master. The Trust submitted a reply on November 9, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report for this claim are now before the court for final determination. See id. Rule 35.

In support of his claim, Mr. Chapman reasserts the arguments that he made in contest. Specifically, Mr. Chapman argues that there is a reasonable medical basis for Dr. Raskin's finding because the surgeon did not report chordae tendineae rupture following his visual observation during surgery. Mr. Chapman also argues that his ingestion of Diet Drugs was the likely cause of his conditions. In addition, Mr. Chapman submitted a declaration prepared by Edward Todd Robbins, M.D., the surgeon who performed claimant's mitral valve surgery. In his declaration, Dr. Robbins explained that "[i]f mitral valve prolapse with chordae rupture and flail of the mural segment were present, then I would have performed simple valve repair and not valve replacement." Finally, Dr. Robbins opined that "Mr. Chapman's nearly 3-month exposure to diet drugs caused pathological changes to his mitral valve and secondary mitral regurgitation. This predisposed him to endocarditis."

In response, the Trust argues that there is no reasonable medical basis for Dr. Raskin's representation that Mr. Chapman did not have chordae tendineae rupture. According to the Trust, Dr. Raskin's Green Form attestations are undermined by various echocardiogram reports that identify chordae tendineae

rupture and the operative report that notes "patient was found to have a flail posterior leaflet." The Trust also contends that the declaration of Dr. Robbins does not establish a reasonable medical basis for Dr. Raskin's representations. Specifically, the Trust notes that "Dr. Robbins fails to address the presence of chordae tendinae rupture" and that his "mere supposition" that he would have "performed simple valve repair and not valve replacement" if mitral valve prolapse with chordae tendineae rupture had been present is not sufficient to refute the findings of the auditing cardiologist.

The Technical Advisor, Dr. Vigilante, reviewed Mr. Chapman's echocardiograms and concluded that there was no reasonable medical basis for Dr. Raskin's finding that Mr. Chapman did not suffer from chordae tendineae rupture. Specifically, Dr. Vigilante stated, in pertinent part, that:

> I reviewed the Claimant's echocardiogram of December 31, 2002.... There was obvious chordae tendinae rupture with partial flailing of the posterior mitral leaflet. A rupture of the chordae tendinae was obvious in both the apical two chamber and apical four chamber views.... The finding of chordae tendinae rupture is consistent with all of the other echocardiograms reviewed. It is also consistent with the operative findings noted in Dr. Robbins' report in which he stated that the patient was found to have a flail posterior leaflet. The finding of chordae tendinae rupture on this study is also consistent with the formal findings noted on the echocardiograms of January 3, 2003 and January 7, 2003....
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> I also reviewed the Claimant's echocardiogram of November 4, 2002 on the same tape.... A ruptured chord was obviously seen in the

> apical two chamber, apical four chamber, and parasternal views....
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> The Claimant's echocardiogram of January 3, 2003 was also noted on the echocardiogram tape.... Once again, there was obvious chordae tendinae rupture with partial flailing of the posterior mitral leaflet....
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> The second echocardiogram tape was reviewed. This tape contained the transesophageal echocardiogram study of November 7, 2002. . . . This also was a very good quality study with very obvious chordae tendinae rupture noted and partial flailing of the posterior mitral leaflet....
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> ....
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> ... [T]here is no reasonable medical basis to answer "no" to Green Form Question D.8. That is, there is obvious chordae tendinae rupture involving the posterior mitral leaflet with partial flailing noted on the echocardiogram of Attestation as well as all of the other studies submitted with the Special Master Record with comments as noted above. An echocardiographer could not reasonably conclude that chordae tendinae rupture was not present on the echocardiogram of Attestation or any of the other studies submitted with the Special Master Record.

In response to the Technical Advisor Report, Mr. Chapman argues that Dr. Vigilante's findings should be disregarded because Dr. Robbins had the advantage of direct examination, which is the "gold standard for characterizing anatomical mitral valve structures." Mr. Chapman also reasserts that the declaration of Dr. Robbins provides a reasonable medical basis for Dr. Raskin's representation that Mr. Chapman did not suffer from chordae tendineae rupture.

Prior to our resolution of his claim, Mr. Chapman passed away. Thus, in August, 2011, Ms. Chapman, personal representative of Mr. Chapman's estate, submitted a supplemental Green Form to the Trust signed by the attesting physician, Dr. Robbins. Based on an echocardiogram dated November 4, 2002, Dr. Robbins attested in Part II of the Green Form that Mr. Chapman suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™ and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. In addition, Dr. Robbins attested that Mr. Chapman died as a result of a condition caused by VHD or valvular repair/replacement surgery. Finally, Dr. Robbins attested that Mr. Chapman suffered a stroke due to (a) bacterial endocarditis contracted after use of Pondimin® and/or Redux™, or (b) chronic atrial fibrillation with left atrial enlargement as defined in Green Form Question F.5., or (c) valvular repair and/or replacement surgery which resulted in a permanent condition which meets the criteria for Functional Level III of the AHA Stroke Outcome Classification System, determined six months or later after the event.[11] Based on such findings, the

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11. Dr. Robbins also attested that Mr. Chapman suffered from bacterial endocarditis associated with moderate or greater mitral regurgitation, arrhythmias, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class III Symptoms. These conditions are not at issue in this claim.

Estate would be entitled to Matrix A-1, Level V[12] benefits in the amount of $1,145,562.[13]

In the supplemental Green Form, Dr. Robbins attested that Mr. Chapman did not suffer from chordae tendineae rupture. In a note on the supplemental Green Form, Dr. Robbins included a portion of the language from his declaration submitted in connection with Mr. Chapman's Green Form. As noted above, a finding of chordae tendineae rupture requires the payment of reduced Matrix Benefits for a claim for damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c). As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us for the supplemental claim is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

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12. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient: (a) qualifies for Level III benefits and suffers a stroke resulting in a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Levels IV or V, determined six moths after the event; (b) suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use ...;" or (c) qualifies for Level III benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement §§ IV.B.2.c.(5)(b)-(d).

13. Mr. Chapman previously was paid Matrix B-1, Level III benefits for his mitral valve claim in the amount of $143,856. According to the Trust, if entitled to Matrix A-1, Level V benefits, the Estate would be entitled to Matrix Benefits in the amount of $1,289,418. The amount at issue, therefore, is the difference between the Matrix B-1, Level III benefits already paid and the amount of the Matrix A-1, Level V benefits.

In March, 2012, the Trust forwarded the claim for review by Alan J. Bier, M.D., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for the attesting physician's findings that Mr. Chapman did not suffer from chordae tendineae rupture.[14] In support of his conclusion, Dr. Bier stated, "A torn chord is seen on pre-operative [echocardiograms] and [transesophageal echocardiograms] and also is described in the reports included in the medical records."

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Audit Rules, the Estate contested this adverse determination.[15] In contest, the Estate argued that the direct visual examination by Mr. Chapman's surgeon provided a reasonable medical basis for the Green Form representation that Mr. Chapman did not have chordae tendineae rupture. In support of its claim, the Estate submitted a letter dated June 10, 2012 from Dr. Raskin, wherein he stated, in relevant part, that:

> Relevant to the Chapman case is the accuracy and reliability of the echocardiographic diagnosis of ruptured mitral chordate [sic]

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14. Dr. Bier, like Dr. Penkala, concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Chapman did not have mitral valve prolapse. As noted above, we need not resolve this issue given our disposition with regard to the issue of chordae tendineae rupture.

15. There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim as well.

tendinae prior to mitral surgery. The "gold standard" to which echocardiography is compared is the surgeon's anatomical and pathological diagnosis especially when it comes to the evaluation of the mitral valve.

....

While [transesophageal echocardiogram] is [an] important tool in pre-operative assessment and has incremental advantages over [transthorasic echocardiograms], it is notable that when direct surgical observation is compared with [transesophageal echocardiograms] errors are possible and the correct anatomic diagnosis can be missed. The discordance between [transesophageal echocardiograms] compared with surgical observations even for ruptured chordae may be clinically relevant and may be as high as 12%. In the Chapman case thin floating echoes were incorrectly diagnosed as evidence of a flail mitral chordae and the differential possibilities related to redundant chordae, thrombotic nonbacterial or bacterial vegetations were not even considered.

....

The intra-operative [transesophageal echocardiogram] mischaracterized the mobile thin echo as a ruptured chordate [sic] as did prior studies. When it comes to mitral valve surgery the correct pre-operative diagnosis has direct relation to the likelihood of a successful valve repair as opposed to valve replacement. The preoperative decision for [mitral valve] repair is an incentive for earlier surgical referral. Directly relevant to the Chapman case and the accuracy of the pre-operative diagnosis is the cardiovascular surgeon, Dr. Robbins' direct anatomical and pathological observations at the time of surgery. His anatomic diagnosis could have confirmed or refuted (as in this case) the preoperative and intra-operative echocardiographic impressions. Clearly no chordae tendinae rupture was ultimately present under direct and focused inspection and the typical associated anatomical

> findings of classic [mitral valve prolapse] with interchordal scalloping or hooding, annular dilatation, elongated or ruptured chordae or flail leaflets were similarly not found.
>
> Typically in cases of chordae rupture one or more chords, usually to a single segment are ruptured causing prolapse or flail of the unsupported mitral segment. In addition, non-ruptured chords are often thinned; leaflets are typically thinned and the mitral annulus dilated. *None of these findings were present*. If the primary lesion is chordae rupture correcting the segmental prolapse (or flail segment) resulting from the ruptured chord is always required. According to Dr[.] Robbins mitral repair would have been [the] preferred operation had mitral chordae rupture, flail leaflet and/ or typical [mitral valve prolapse] been confirmed at the time of the mitral surgery.
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> ....
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> The thin mobile echo described by previous observers as a "flail or ruptured chord" was wrong and the mobile echo finding actually represented a mobile vegetation(s)....

Although not required to do so, the Trust forwarded the Estate's claim to the auditing cardiologist for a second review. Dr. Bier submitted a declaration in which he affirmed his previous finding that there was no reasonable medical basis for the Green Form representation that Mr. Chapman did not have chordae tendineae rupture. In his declaration, Dr. Bier stated, in relevant part, that:

> There is also clear evidence on multiple [echocardiograms] of a mobile structure consistent with a torn chord. Though Dr. Raskin suggests this is actually a vegetation, it is unlikely to be vegetation based on its thin, filamentous appearance. The intraoperative [transesophageal

> echocardiogram] shows this torn chord, so if it was vegetation, it is difficult to imagine that it happened to embolize during the relatively short time from the [echocardiogram] until the specimen went to pathology. Despite the surgeon's description, the pathology report - certainly a higher standard than the surgeon's visual inspection - describes "slight thickening with no calcification or vegetation" and "fibrous and focal myxoid changes," more suggestive of [mitral valve prolapse] than active endocarditis. I agree with Dr. Raskin that with careful inspection, at the time of surgery, a torn chord should have been visualized. I have reviewed the surgeon's operative note dated January 7, 2003. His visual description states there are "endocarditic changes over both leaflets". He also describes a "tremendous amount of change secondary to the patient's Fen Phen ingestion." He does not specifically comment about the presence or absence of a torn chord, but does indicate that the leaflet was flail on the intraoperative transesophageal echocardiogram. Based upon all of the above, I affirm my audit finding, that there is no reasonable medical basis to conclude that Mr. Chapman did not have chordae tendinae rupture.

The Trust then issued a final post-audit determination again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's supplemental claim should be paid. On November 8, 2012, we issued an Order to show cause and

referred the matter to the Special Master for further proceedings. See PTO No. 8959 (Nov. 8, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on February 22, 2013. The Show Cause Record for the Estate's claim is now before the court for final determination. See id. Rule 35.

In support of its claim, the Estate reasserts the arguments that it made in contest. The Estate also contends that the statement of Dr. Robbins that he did not find chordae tendineae rupture during Mr. Chapman's mitral valve surgery is "determinative" of its claim because direct medical observation is the "gold standard" and the "best evidence."[16] In response, the Trust argues that the Estate has not established a reasonable medical basis for the representation of Dr. Robbins that Mr. Chapman did not have chordae tendineae rupture.

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16. In addition, the Estate requested that a Technical Advisor be assigned to review its claim. Given that Dr. Vigilante already reviewed the relevant echocardiograms and medical records in connection with Mr. Chapman's claim, it was not necessary to appoint a Technical Advisor. We also reject the Estate's assertion that only a Board-Certified cardiothoracic surgeon is competent to evaluate the Estate's claim. This argument ignores that the Estate itself relies on Dr. Raskin, who is not a Board-Certified cardiothoracic surgeon, and that Mr. Chapman's echocardiograms and other medical records were appropriately reviewed by Dr. Vigilante.

The issue presented for resolution of these claims is whether claimants met their burden of proving that there is a reasonable medical basis for the attesting physicians' findings that Mr. Chapman did not have chordae tendineae rupture. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in the Green Forms at issue, we must affirm the Trust's final determinations and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claims in accordance with the Settlement Agreement. See id. Rule 38(b).

After reviewing the entirety of the Show Cause Records for both claims, we find Mr. Chapman's and the Estate's arguments are without merit. As an initial matter, neither Mr. Chapman nor the Estate adequately contests the findings of Dr. Penkala, Dr. Bier, and Dr. Vigilante that numerous echocardiographic studies of Mr. Chapman's mitral valve demonstrated chordae tendineae rupture.

Specifically, Dr. Penkala stated that "despite the limitations of this [December 31, 2002] study there appears to be a ruptured chord to the posterior [mitral valve] leaflet with a region of prolapse/partial flail." Dr. Penkala also observed that the chordae tendineae rupture "was subsequently seen much

more clearly on the [transesophageal echocardiogram] dated 1/7/03."[17]

Dr. Bier also found that "[a] torn chord is seen on pre-operative [echocardiograms] and [transesophageal echocardiograms] and also is described in the reports included in the medical records." In addition, Dr. Bier explained:

> There is also clear evidence on multiple echoes of a mobile structure consistent with a torn chord. Though Dr. Raskin suggests this is actually a vegetation, it is unlikely to be vegetation based on its thin, filamentous appearance. The intraoperative [transesophageal echocardiogram] shows this torn chord, so if it was a vegetation, it is difficult to imagine that it happened to embolize during the relatively short time from the echo until the specimen went to pathology.

Similarly, Dr. Vigilante observed that Mr. Chapman's December 31, 2002 echocardiogram demonstrated chordae tendineae rupture. Dr. Vigilante noted that "[a] rupture of the chordae tendinae was obvious in both the apical two chamber and apical four chamber views." Dr. Vigilante further observed that the echocardiographic studies of November 4, 2002, November 7, 2002, and January 3, 2003 each demonstrated "obvious" chordae tendineae rupture.

Despite opportunities to rebut these specific findings, Mr. Chapman and the Estate, relying on statements of Dr. Raskin and a declaration of Dr. Robbins, simply argue that the absence

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17. Thus, we reject claimant's argument that Dr. Penkala's review did not provide the Trust with a sufficient basis for finding that Mr. Chapman suffered from chordae tendineae rupture.

of a finding of chordae tendineae rupture on visual observation during Mr. Chapman's mitral valve replacement should be substituted for the numerous echocardiographic studies demonstrating "obvious" chordae tendineae rupture. We disagree. Although Dr. Robbins does affirmatively state in his declaration that he did not observe during claimant's surgical procedure that Mr. Chapman suffered from mitral valve prolapse, he did not make such an unequivocal statement with respect to chordae tendineae rupture.[18] Rather, with respect to chordae tendineae rupture, Dr. Robbins only stated that "[i]f mitral valve prolapse with chordae rupture and flail of the mural segment were present, then I would have performed simple valve repair and not valve replacement."[19] Dr. Vigilante observed, however, that "[t]he finding of chordae tendinae rupture is ... consistent with the operative findings noted in Dr. Robbins' report in which he stated that the patient was found to have a flail posterior leaflet." Although claimant responded to the Technical Advisor Report, he did not address the inconsistency between the declaration of Dr. Robbins and his operative report.

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18. Dr. Robbins also expressed no opinions as to the presence of chordae tendineae rupture on Mr. Chapman's echocardiograms.

19. We also reject Mr. Chapman's and the Estate's arguments that the direct visual observation of a surgeon must be "determinative" of the presence of the condition of chordae tendineae rupture because nothing in the Settlement Agreement supports such an argument. In any event, as Dr. Robbins did not definitively state that he did not observe chordae tendineae rupture on visual inspection, this argument is irrelevant to our disposition.

We also disagree that Dr. Raskin's opinion that the repeated finding of chordae tendineae rupture on Mr. Chapman's echocardiograms was simply "wrong" or a "misdiagnosis" provides a reasonable medical basis for the attesting physicians' findings because that opinion is contradicted by Mr. Chapman's medical records. In addition, the Technical Advisor confirmed that chordae tendineae rupture was apparent on all of the echocardiograms and was noted on the operative report for his mitral valve surgery. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if a claimant has chordae tendineae rupture. We must apply the Settlement Agreement as written.

Finally, to the extent Mr. Chapman and the Estate argue that they may avoid application of a reduction factor by asserting that Mr. Chapman's injuries were caused by his ingestion of Diet Drugs, such argument is misplaced. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to show that they meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the condition at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if claimant is diagnosed as having chordae tendineae rupture. We must apply the Settlement Agreement as written. Accordingly, Mr. Chapman's and the Estate's assertions that the cause of Mr. Chapman's injuries was his ingestion of Diet Drugs is irrelevant to the issue before the court.

For the foregoing reasons, we conclude that neither Mr. Chapman nor his Estate has met their burden of proving that there is a reasonable medical basis for finding that Mr. Chapman did not suffer from chordae tendineae rupture. Therefore, we will affirm the Trust's denial of Mr. Chapman's original claim for Matrix A, Level III benefits and the related derivative claim submitted by his spouse. We also will affirm the Trust's denial

of the Estate's supplemental claim for Matrix A-1, Level V benefits.[20]

20. Accordingly, the Motion for Authorization and Instruction for AHP Settlement Trust to Pay Robert Chapman on His Matrix Claim, which claimant filed on April 8, 2010, will be denied.